

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: TRICOR DIRECT PURCHASER
ANTITRUST LITIGATION

Civil Action No.: 05-340 (KAJ)
(Consolidated)

THIS DOCUMENT RELATES TO:
C.A. No. 05-404 (KAJ)

ANSWER BY FOURNIER

FOURNIER'S ANSWER TO THE WALGREEN AMENDED COMPLAINT

Respondents, Fournier Industrie et Santé and Laboratoires Fournier S.A. (collectively, "Fournier"), by their undersigned attorneys, answer to Walgreen Co., Eckerd Corporation, The Kroger Co., Maxi Drug, Inc. d/b/a Brooks Pharmacy, Albertson's, Inc., Safeway, Inc., and Hy-Vee, Inc.'s Amended Complaint and Demand for Jury Trial ("Walgreen Complaint"), on knowledge as to themselves and otherwise on information and belief, as follows:

1. Admitted that Fournier manufactures a fenofibrate drug product marketed by Abbott under the trade name TriCor and that the first sentence of paragraph 1 provides a non-exhaustive description of TriCor. To the extent paragraph 1 contains a description of this proceeding and conclusions of law, no response is required. Otherwise denied.

2. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 2 and, therefore, denies these allegations.

3. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 3 and, therefore, denies these allegations.

4. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 4 and, therefore, denies these allegations.

5. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 5 and, therefore, denies these allegations.

6. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 6 and, therefore, denies these allegations.

7. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 7 and, therefore, denies these allegations.

8. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 8 and, therefore, denies these allegations.

9. Admitted.

10. Admitted.

11. Denied.

12. Admitted that this Court has jurisdiction over the alleged subject matter of this litigation. To the extent paragraph 12 contains a description of this proceeding and conclusions of law, no response is required. Otherwise denied.

13. Denied.

14. Admitted that TriCor is sold in interstate commerce. Otherwise denied.

15. To the extent that Walgreen's averments state economic conclusions, no response is required. Otherwise denied.

16. To the extent that Walgreen's averments state economic or legal conclusions, no response is required. Otherwise denied.

17. To the extent that Walgreen's averments state economic conclusions, no response is required. Otherwise denied.

18. To the extent that Walgreen's averments state economic conclusions, no response is required. Otherwise denied.

19. To the extent that Walgreen's averments state economic or legal conclusions, no response is required. Otherwise denied.

20. Denied.

21. Denied.

22. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

23. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent that Walgreen's averments intend to recite from the D.C. Circuit's opinion in Mova Pharmaceuticals Corp. v. Shalala, 140 F.3d 1060, 1068 (D.C. Cir. 1998), the opinion speaks for itself. Otherwise denied.

24. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

25. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

26. To the extent that Walgreen's averments state economic conclusions, no response is required. Otherwise denied.

27. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

28. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

29. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

30. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

31. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

32. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

33. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

34. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

35. Admitted that paragraph 35 provides a non-exhaustive description of TriCor.

36. Admitted that fenofibrate is a fibrate and that fibrates, statins, bile acid sequestrants, and niacin may be used to address cholesterol conditions. Otherwise denied.

37. Admitted that fenofibrate has been known to be a cholesterol-lowering agent since at least the early 1980's and that Fournier's fenofibrate-based drug product Lipidil was approved for use in the United States by at least 1993. Otherwise denied.

38. Admitted.

39. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the prosecution history or reexamination history of the '726 Patent, the prosecution history and reexamination history speak for themselves. Otherwise denied.

40. Admitted that in December 1999, Fournier filed for reexamination of the '726 Patent. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the prosecution history or reexamination history of the '726 Patent, the prosecution history and reexamination history speak for themselves. Otherwise denied.

41. Admitted that in 1997 Fournier granted Abbott an exclusive license to the '726 Patent in the United States; the FDA approved the TriCor 67 mg capsule on February 9, 1998; the FDA approved TriCor 134 mg and 200 mg capsules on June 30, 1999; and sales of TriCor exceeded \$150 million in 2000 and \$277 million in 2001. Otherwise denied.

42. Admitted that Novopharm filed an ANDA with the FDA on or about December 14, 1999 for fenofibrate capsules; Novopharm submitted a Paragraph IV certification; and that Novopharm subsequently amended that ANDA. To the extent that Walgreen's averments intend to recite the ANDA and Paragraph IV certification, those documents speak for themselves. Otherwise denied.

43. Admitted that Impax filed an ANDA with the FDA on or about May 9, 2000 and submitted Paragraph IV certifications. To the extent that Walgreen's averments intend to recite the ANDA and Paragraph IV certification, those documents speak for themselves. Otherwise denied.

44. Admitted that Abbott and Fournier filed complaints alleging infringement of the '726 Patent against Teva and Impax in the United States District Court for the District of Illinois on or about April 7, 2000, August 18, 2000, and March 19, 2001. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

45. Admitted that the FDA granted Impax tentative approval for Impax's fenofibrate capsules on February 20, 2002. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

46. Admitted that the Illinois District Court granted summary judgment of non-infringement in favor of Teva and that, on March 20, 2003, the U.S. Court of Appeals for the Federal Circuit ruled on the appeal of the trial court's decision in Abbott Laboratories v. Novopharm Ltd., 2002 WL 433584 (N.D. Ill. Mar. 20, 2002). To the extent Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the trial court's opinion in Abbott Laboratories v. Novopharm Ltd., 2002

WL 433584 (N.D. Ill. Mar. 20, 2002), or from the Federal Circuit's opinion, the opinions speak for themselves. Otherwise denied.

47. Admitted that Teva received final FDA approval to market its 134 mg and 200 mg fenofibrate capsule product on April 9, 2002, tentative approval to market its 67 mg fenofibrate capsule product on April 9, 2002, and final approval to market its 67 mg fenofibrate capsule product on September 3, 2002. Otherwise denied.

48. Admitted that on March 26, 2003, the Illinois District Court granted Impax's motion for summary judgment for the reasons stated in the opinion issued by that court, and on or about October 28, 2003, the FDA granted Impax final approval to market its fenofibrate capsules. Otherwise denied.

49. Denied.

50. Denied.

51. Admitted that on September 4, 2001, Abbott obtained FDA approval to market the 54 mg and 160 mg tablet TriCor formulation and that Abbott had previously marketed the 67 mg and 200 mg capsule TriCor formulation. Otherwise denied.

52. Admitted that the TriCor capsule formulation was discontinued and that the discontinuance was communicated to the public. Otherwise denied.

53. Denied.

54. Denied.

55. Admitted that TriCor may be used as a maintenance medication. Otherwise denied.

56. Admitted that, in April 2002, Teva received final FDA approval to market its 134 mg and 200 mg fenofibrate capsule product. Otherwise denied.

57. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 57 and, therefore, denies these allegations.

58. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 58 and, therefore, denies these allegations.

59. Admitted that Abbott communicated the discontinuance of the TriCor capsule formulation to First DataBank. Otherwise denied.

60. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments in paragraph 60 and, therefore, denies these allegations. Otherwise denied.

61. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments relating to third-party plans and pharmacist practice, and therefore denies them. Otherwise denied.

62. Admitted that the original TriCor tablets were bioequivalent to the TriCor capsules and had common clinical studies. Otherwise denied.

63. Admitted that Abbott sought and obtained from the FDA an additional indication for the TriCor tablet formulation that the capsule formulation did not have, and in

support of that application Abbott relied on clinical studies conducted in connection with the capsule formulation. To the extent Walgreen's averments intend to recite from correspondence originating from the FDA, the document speaks for itself. Otherwise denied.

64. Denied.

65. Denied.

66. Denied.

67. Admitted that Abbott and Fournier invested resources developing and obtaining FDA approval for the 54 mg and 160 mg TriCor tablet formulations. Otherwise denied.

68. Denied.

69. Denied.

70. Denied.

71. Admitted that Teva filed an ANDA for 54 mg and 160 mg fenofibrate tablets; that said ANDA contained Paragraph IV certifications for the '726 Patent and U.S. Patent Nos. 6,074,670 (the "'670 Patent") and 6,277,405 (the "'405 Patent"); and notice of Teva's Paragraph IV certification was received by Fournier and Abbott. Otherwise denied.

72. Admitted that U.S. Patent Nos. 6,589,552 (the "'552 Patent") and 6,652,881 (the "'881 Patent") subsequently issued; Teva filed Paragraph IV certifications for the '552 and '881 Patents; and Abbott and Fournier received notice of the Paragraph IV

certifications; and Abbott and Fournier filed suit against Teva on the '552 and '881 Patents within 45-days after receiving such notice. Otherwise denied.

73. Admitted.

74. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

75. Admitted that Impax filed an ANDA for fenofibrate tablets on or about December 2002; the ANDA contained Paragraph IV certifications; Abbott and Fournier filed a complaint against Impax alleging infringement of the '670 and '405 Patents on January 23, 2003; and that subsequent suits asserting the '552 and '881 Patents were filed. To the extent that Walgreen's remaining averments state legal conclusions, no response is required. Otherwise denied

76. Admitted that on March 5, 2004, the FDA granted tentative approval to Teva and Impax's ANDA's for 54 mg and 160 mg fenofibrate tablets, and that Teva and Impax have represented to this Court that, absent the 30-month stays, they would have received final approval from the FDA on March 5, 2004 and would have entered the market shortly thereafter. Otherwise denied.

77. Fournier is without sufficient information or knowledge to form a belief as to the truth of the averments concerning Teva and Impax's likely conduct, and therefore denies them. Otherwise denied.

78. Admit only that Teva, Impax, Abbott and Fournier agreed to modifications of the original trial schedule; on May 20, 2005, Abbott and Fournier moved to voluntarily

dismiss the patent infringement complaint and Teva's and Impax's counterclaims; and Teva, Impax, Abbott and Fournier jointly stipulated to a dismissal of the patent infringement claims and counterclaims. Otherwise denied.

79. Denied.

80. Admitted that Abbott and Fournier asserted the '726 Patent against Teva and Impax in the Illinois Patent Litigation. Otherwise denied.

81. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the prosecution history or reexamination history of the '726 Patent, the prosecution history and reexamination history speak for themselves. Otherwise denied.

82. To the extent that Walgreen's averments intend to summarize Novopharm's or Teva's capsule ANDA or Paragraph IV certification, those documents speak for themselves. Otherwise denied.

83. Denied.

84. Admitted that the Illinois District Court granted summary judgment for Teva on the '726 Patent infringement claims. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent that Walgreen's averments intend to recite from the District Court or Federal Circuit's opinion, those opinions speak for themselves. Otherwise denied.

85. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the trial court's opinion in Abbott Laboratories v. Impax Laboratories, Inc., 2003 WL 1563426 (N.D. Ill. 2003), the opinion speaks for itself. Otherwise denied.

86. Admitted that Abbott and Fournier initiated the patent infringement action against Teva for infringement of the '726, '670, '405, '552, and '881 Patents. Otherwise denied.

87. Admitted that Teva provided Abbott and Fournier with technical materials from its ANDA statements in connection with its Paragraph IV certifications. Otherwise denied.

88. Denied.

89. Denied.

90. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

91. To the extent Walgreen's averments intend to recite from the Stamm Patents, the *Markman* rulings, and other filings in the Tablet litigations, these documents speak for themselves. Otherwise denied.

92. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

93. Admitted that the '881 Patent resulted from Application No. 10/288,425, filed November 6, 2002; and that the '881 Patent is assigned to Fournier. To the extent

Walgreen's averments intend to recite from the '881 Patent or its prosecution history, the Patent and its prosecution history speak for themselves. Otherwise denied.

94. Admitted that Fournier is the owner of the '726 Patent. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the prosecution history or reexamination history of the '726 Patent, the prosecution history and reexamination history speak for themselves. Otherwise denied.

95. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the '881 Patent or its prosecution history, the '881 Patent and its prosecution history speak for themselves. Otherwise denied.

96. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the '881 Patent or its prosecution history, the '881 Patent and its prosecution history speak for themselves. Otherwise denied.

97. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the '881 Patent or its prosecution history, the '881 Patent and its prosecution history speak for themselves. Otherwise denied.

98. Admitted.

99. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the '881 Patent or its prosecution history, the '881 Patent and its prosecution history speak for themselves. Otherwise denied.

100. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the '881 Patent or its prosecution history, the '881 Patent and its prosecution history speak for themselves. Otherwise denied.

101. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from unidentified Fournier documents, the documents speak for themselves. Otherwise denied.

102. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the '881 Patent or its prosecution history, the '881 Patent and its prosecution history speak for themselves. Otherwise denied.

103. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the '881 Patent or its prosecution history, the '881 Patent and its prosecution history speak for themselves. Otherwise denied.

104. To the extent that Walgreen's averments state legal conclusions, no response is required. To the extent Walgreen's averments intend to recite from the '881 Patent

or its prosecution history, the '881 Patent and its prosecution history speak for themselves. Otherwise denied.

105. To the extent that Walgreen's averments state legal conclusions, no response is required. Otherwise denied.

106. Admitted that Reginault signed an inventor's oath in connection with the '726 Patent. To the extent Teva's averments intent to recite from the inventor's oath, the '726 Patent, the '881 Patent, or their prosecution history, the oath, Patents, and prosecution history speak for themselves. To the extent that Teva's averments state legal conclusions, no response is required. Otherwise denied.

107. Denied.

108. Denied.

109. Denied.

110. Denied.

111. Admitted that Abbott obtained FDA approval to market a new tablet TriCor formulation in 48 mg and 145 mg strengths on November 5, 2004, and the new tablet formulation contains the same active ingredient, fenofibrate. Otherwise denied.

112. Admitted that the new 48 and 145 mg strength tablet formulation allows patients to take TriCor other than with meals, was developed using patented nanotechnology licensed by Elan Corporation, Plc, and that the patent license obtained from Elan was exclusive for the field of fenofibrate dosage forms. Otherwise denied.

113. Admitted that Abbott discontinued marketing the TriCor original tablet formulation after the new tablet formulation became available and communicated the tablet discontinuance to the public. Otherwise denied.

114. Denied.

115. Admitted that Abbott under certain circumstances accepted returns of the original tablet formulation. Otherwise denied.

116. Denied.

117. Denied.

118. Denied.

119. Denied.

120. Admitted that the relevant geographic market is the United States. Otherwise denied.

121. Denied.

122. Denied.

COUNT I

123. Fournier repeats and realleges its responses herein to paragraphs 1-122 in answer to paragraph 123.

124. Denied.

125. Denied.

126. Denied.

127. Denied.

128. Denied.

COUNT II

129. Fournier repeats and realleges its responses herein to paragraphs 1-128 in answer to paragraph 129.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Denied.

136. Denied.

137. Denied.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs fail to state a claim against Fournier upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs have not suffered, and will not suffer, injury of the type that the antitrust laws are designed to prevent, or any other injury to a legally cognizable interest, by reason of the conduct alleged in the Walgreen Complaint.

THIRD AFFIRMATIVE DEFENSE

At all times, Fournier has acted in good faith in furtherance of its legitimate business interests and has caused no injury to competition, the public, or plaintiffs.

FOURTH AFFIRMATIVE DEFENSE

Fournier's conduct is protected under the Noerr-Pennington doctrine and/or otherwise under the Constitution of the United States.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are precluded, in whole or in part, by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984 and related amendments.

SIXTH AFFIRMATIVE DEFENSE

To the extent there is a finding of conduct that prevented generic entry and higher prices as a result, plaintiffs' claims are barred, in whole or in part, to the extent any higher prices were passed on, in whole or in part, to parties not included in this action

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs would be unjustly enriched if allowed to recover all or any part of the damages alleged in the Walgreen Complaint.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims fail to comply with the pleading requirements of Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs did not suffer injury or damages by reason of any act or omission by Fournier.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs failed to mitigate their damages.

ELEVENTH AFFIRMATIVE DEFENSE

Any injuries, losses, or damages suffered by plaintiffs were proximately caused by their own actions regardless of whether contributory, negligent, incompetent, careless or reckless.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs alleged damages, if any, are speculative.

THIRTEENTH AFFIRMATIVE DEFENSE

Venue does not lie in this district as to the claims against Fournier.

FOURTEENTH AFFIRMATIVE DEFENSE

Fournier does not maintain monopoly power in the relevant market.

FIFTEENTH AFFIRMATIVE DEFENSE

The Food and Drug Administration approved each version of TriCor for sale in the United States.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because they contravene the rule of law established by the United States Supreme Court in Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977).

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statute of limitations and/or laches.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because of waiver and/or estoppel.

NINETEENTH AFFIRMATIVE DEFENSE

Fournier reserves the right to add to its affirmative defenses as additional information becomes available in the course of this litigation.


RELIEF REQUESTED

WHEREFORE, Fournier, having answered, respectfully requests judgment dismissing with prejudice the Walgreen Complaint and each and every claim for relief therein, and awarding Fournier its costs, disbursements, attorneys' fees and such other and further relief as the Court deems just and proper.

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Dated: July 21, 2006

CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2006, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on July 21, 2006, I sent by electronic mail the foregoing document to the following non-registered participants:

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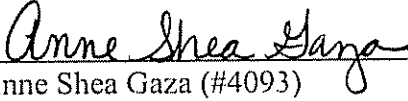
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